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Counsel for Defendants
Lupin Limited and Lupin Pharmaceuticals, Inc.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ELAN PHARMA INTERNATIONAL LTD. and FOURNIER LABORATORIES IRELAND LTD., Plaintiffs, v. LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC., Defendants.	C.A. No. 2:09-cv-01008-JAG-MCA

LUPIN LIMITED AND LUPIN PHARMACEUTICALS, INC.'S
ANSWER, DEFENSES AND COUNTERCLAIMS

Defendants Lupin Limited and Lupin Pharmaceuticals, Inc. ("LPI") (collectively, "Lupin") hereby answer the Complaint of Plaintiffs, Elan Pharma International Ltd. ("Elan") and Fournier Laboratories Ireland Ltd. ("Fournier"), as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent Nos. 7,276,249 ("the '249 patent") and 7,320,802 ("the '802 patent"). This action arises out of Defendants' filing of an Abbreviated New Drug Application ("ANDA") seeking approval to sell generic copies of the highly successful TRICOR® 48 mg and 145 mg products prior to the expiration of Plaintiffs' patents.

ANSWER: Paragraph 1 contains legal conclusions to which no answer is required. To the extent that an answer is required, Lupin admits that this is an action for alleged infringement of United States Patent Nos. 7,276,249 ("the '249 patent") and 7,320,802 ("the '802 patent"). Lupin further admits that Lupin Ltd. has filed an ANDA seeking United States Food and Drug Administration ("FDA") approval for Fenofibrate Tablets, 48 mg and 145 mg, prior to the expiration of the '249 and '802 patents. Lupin denies all remaining allegations in Paragraph 1.

THE PARTIES

2. Plaintiff Elan Pharma International Ltd. is an Irish corporation having a principal place of business at Monksland, Athlone, Co. Westmeath, Ireland.

ANSWER: Lupin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2, and therefore denies all such allegations.

3. Plaintiff Fournier Laboratories Ireland Ltd. is an Irish corporation having a principal place of business at Anngrove, Carrigtwohill, Co. Cork, Ireland.

ANSWER: Lupin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3, and therefore denies all such allegations.

4. On information and belief, Lupin Ltd. is an Indian corporation having a place of business at B/4 Laxmi Towers, Bandra-Kurla Complex, Bandra (W), Mumbai 400 051, India, and having a registered office at 159 CST Road, Kalina, Santacruz (E), Mumbai 400 098, India. On information and belief, Lupin Ltd. is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products through various operating subsidiaries, including Lupin Pharmaceuticals.

ANSWER: Lupin admits that Lupin Ltd. is an Indian corporation having a place of business and registered office located solely in India. Lupin denies all remaining allegations in Paragraph 4.

5. On information and belief, Lupin Pharmaceuticals is a corporation organized and existing under the laws of the Commonwealth of Virginia, having a place of business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland, 21202. On information and belief, Lupin Pharmaceuticals is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the U.S. market. Lupin Pharmaceuticals in a wholly-owned subsidiary of Lupin Ltd.

ANSWER: Paragraph 5 contains legal conclusions to which no answer is required. To the extent that an answer is required, Lupin admits that LPI is a Virginia corporation having a place of business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland, 21202. Lupin further admits that LPI is a wholly-owned subsidiary of Lupin Ltd. Lupin denies all remaining allegations in Paragraph 5.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Paragraph 6 contains legal conclusions to which no answer is required. To the extent that an answer is required, Lupin avers that subject matter jurisdiction is proper only for the claims directed solely against Lupin Ltd. under 35 U.S.C. § 271(e)(2)(A). Lupin denies all remaining allegations in Paragraph 6.

7. On information and belief, this Court has personal jurisdiction over Lupin Ltd. because Lupin Ltd. has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Lupin Ltd. has had persistent and continuous contacts with this judicial district, including developing and/or manufacturing pharmaceutical products that are sold in this judicial district.

ANSWER: Paragraph 7 contains legal conclusions to which no answer is required. To the extent that an answer is required, Lupin denies the allegations in Paragraph 7. Answering

further, to conserve the resources of the parties and the Court, Lupin Ltd. does not contest personal jurisdiction for purposes of this action only.

8. On information and belief, this Court has personal jurisdiction over Lupin Pharmaceuticals because Lupin Pharmaceuticals has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Lupin Pharmaceuticals has had persistent and continuous contacts with this judicial district, including developing, manufacturing, and/or selling pharmaceutical products that are sold in this judicial district.

ANSWER: Paragraph 8 contains legal conclusions to which no answer is required. To the extent that an answer is required, Lupin denies the allegations in Paragraph 8. Lupin further avers LPI is not a proper party to this suit. Answering further, to conserve the resources of the parties and the Court, LPI does not contest personal jurisdiction for purposes of this action only.

9. On information and belief, Lupin Pharmaceuticals participated in, contributed to, aided, abetted, and/or induced the submission to the United States Food and Drug Administration ("FDA") of the ANDA at issue in this case.

ANSWER: Denied.

10. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals operate as an integrated, unitary business. For example, Lupin Ltd. includes within its Annual Report the activities of Lupin Pharmaceuticals, including revenue earned.

ANSWER: Denied.

11. On information and belief, Lupin Pharmaceuticals is registered to do business in New Jersey.

ANSWER: Paragraph 11 contains legal conclusions to which no answer is required. To the extent that an answer is required, Lupin admits that LPI is registered to do business in New Jersey. Lupin denies all remaining allegations in Paragraph 11.

12. On information and belief, Lupin Pharmaceuticals has appointed National Registered Agents, Inc. of Princeton, New Jersey, as its registered agent for the receipt of service of process.

ANSWER: Paragraph 12 contains legal conclusions to which no answer is required. To the extent that an answer is required, Lupin admits that LPI has appointed National

Registered Agents, Inc. of Princeton, New Jersey, as its registered agent in New Jersey for the receipt of service of process. Lupin denies all remaining allegations in Paragraph 12.

13. Lupin Ltd. and Lupin Pharmaceuticals stipulated in a previous litigation to personal jurisdiction in this Court. *See* Dec. 17, 2006 Stipulation and Order, *Sepracor Inc. v. Sun Pharmaceutical Industries Ltd.*, Case No. 07-4213 (D.N.J.).

ANSWER: Paragraph 13 contains legal conclusions to which no answer is required. To the extent that an answer is required, Lupin denies the allegations in Paragraph 13.

14. Two related lawsuits are currently pending in this Court. On February 29, 2008, Elan and Fournier filed suit in this Court against Teva Pharmaceuticals USA, Inc. ("Teva") seeking a judgment that each of the '249 and '802 patents, in addition to one other patent, is infringed by Teva's filing of its ANDA No. 90-069. *See Elan Pharma International Ltd. and Fournier Laboratories Ireland Ltd. v. Teva Pharmaceuticals USA, Inc.*, Case No. 08-1085 (D.N.J.). On November 3, Elan and Fournier filed suit in this Court against Biovail Laboratories International SRL and Biovail Corporation (collectively "Biovail") seeking a judgment that each of the '249 and '802 patents, in additional to one other patent, is infringed by Biovail's filing of its ANDA No. 90-715. *See Elan Pharma International Ltd. and Fournier Laboratories Ireland Ltd. v. Biovail Laboratories International SRL and Biovail Corp.*, Case No. 08-5412 (D.N.J.).

ANSWER: Paragraph 14 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 14, and therefore denies all such allegations.

15. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

ANSWER: Paragraph 15 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin denies the allegations in Paragraph 15. Answering further, to conserve the resources of the parties and the Court, Lupin does not contest venue in this district for purposes of this action only.

BACKGROUND

16. On October 2, 2007, the '249 patent, entitled "Nanoparticulate Fibrate Formulations," was duly and legally issued to Elan and Fournier as assignees. A true and correct copy of the '249 patent is attached as Exhibit A.

ANSWER: Paragraph 16 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that, according to the electronic records of the U.S. Patent and Trademark Office ("PTO"), on October 2, 2007, the PTO issued the '249 patent, entitled "Nanoparticulate Fibrate Formulations." Lupin avers that the cover page of the '249 patent identifies "Elan Pharma International, Ltd." and "Fournier Laboratories Ireland Ltd." as the purported "assignees," and that what purports to be a copy of the '249 patent is attached to the Complaint as Exhibit A. Lupin denies the remaining allegations in Paragraph 16. Lupin further denies that the '249 patent was "duly and legally issued."

17. On January 22, 2008, the '802 patent, entitled "Methods of Treatment Using Nanoparticulate Fenofibrate Compositions," was duly and legally issued to Elan and Fournier as assignees. A true and correct copy of the '802 patent is attached as Exhibit B.

ANSWER: Paragraph 17 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that, according to the electronic records of the PTO, on January 22, 2008, the PTO issued the '802 patent, entitled "Methods of Treatment Using Nanoparticulate Fenofibrate Compositions." Lupin avers that the cover page of the '802 patent identifies "Elan Pharma International, Ltd." and "Fournier Laboratories Ireland Ltd." as the purported "assignees," and that what purports to be a copy of the '802 patent is attached to the Complaint as Exhibit B. Lupin denies the remaining allegations in Paragraph 17. Lupin further denies that the '802 patent was "duly and legally issued."

18. On November 5, 2004, the FDA approved New Drug Application ("NDA") No. 21-656 for TRICOR® tablets, which contain fenofibrate, under § 505(a) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(a), as adjunctive therapy to diet for treatment of adult patients with hypertriglyceridemia and to reduce elevated LDL-C, Total-C, Triglycerides and

Apo B, and to increase HDL-C in adult patients with primary hypercholesterolemia, or mixed dyslipidemia.

ANSWER: Paragraph 18 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin avers that the electronic version of FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book") states that New Drug Application ("NDA") No. 21-656 for TRICOR® (fenofibrate) Tablets 48 mg and 145 mg was approved on or about November 5, 2004, and that any approved indications for TRICOR® (fenofibrate) Tablets are set forth in the FDA-approved labeling for that drug product. Lupin denies all remaining allegations in Paragraph 18.

19. The '249 and '802 patents are listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for TRICOR® tablets.

ANSWER: Paragraph 19 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that FDA's Orange Book lists the '249 and '802 patents in connection with TRICOR® Tablets. Lupin denies all remaining allegations in Paragraph 19.

20. On information and belief, Lupin Ltd., itself and/or through its subsidiary, agent and alter ego, Lupin Pharmaceuticals, submitted ANDA No. 90-856 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of fenofibrate tablets in 48 mg and 145 mg dosages ("Lupin's Tablets, 48 mg and 145 mg"), as generic versions of the TRICOR® 48 mg and 145 mg tablets. Upon information and belief, Lupin Pharmaceuticals will market and/or distribute Lupin's Tablets, 48 mg and 145 mg, if ANDA No. 90-856 is approved by the FDA.

ANSWER: Paragraph 20 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that Lupin Ltd. submitted an ANDA to FDA for Fenofibrate Tablets, 48 mg and 145 mg. Lupin denies that LPI submitted such an ANDA. Lupin denies all remaining allegations in Paragraph 20.

21. By letter dated January 22, 2009, Lupin Ltd. advised Elan and Fournier that it had submitted ANDA No. 90-856 seeking approval to manufacture, use, or sell Lupin's Tablets, 48 mg and 145 mg, prior to the expiration of the '249 and '802 patents.

ANSWER: Lupin admits that Lupin Ltd. sent the required notice of its ANDA, dated January 22, 2009 ("Lupin Ltd.'s Notice Letter"), to Plaintiffs, among others. Lupin avers that Lupin Ltd.'s Notice Letter satisfies all statutory and regulatory requirements. Lupin denies all remaining allegations in Paragraph 21.

22. The January 22, 2009 letter also advised Elan and Fournier that Lupin's ANDA included a certification under 21 U.S.C. § 355(j)(2)(vii)(IV) that, in Lupin's opinion, the '249 and '802 patents are invalid and/or will not be infringed by the commercial manufacture, use, or sale of Lupin's Tablets, 48 mg and 145 mg.

ANSWER: Lupin admits that Lupin Ltd.'s Notice Letter contains, *inter alia*, the information required by statute and regulation, including notice that Lupin Ltd.'s ANDA contains a so-called "paragraph IV certification" stating that the '249 and '802 patents are invalid, unenforceable and/or not infringed. Lupin denies all remaining allegations in Paragraph 22.

COUNT I

23. Plaintiffs incorporate each of the preceding paragraphs 1-22 as if fully set forth herein.

ANSWER: Lupin repeats, reasserts and incorporates by reference its answers to Paragraphs 1 through 22 above as if fully set forth herein.

24. By filing ANDA No. 90-856 for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Lupin's Tablets, 48 mg and 145 mg, prior to the expiration of the '249 patent, Defendants have committed an act of infringement, and/or induced infringement, of the '249 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Denied.

25. The commercial manufacture, use, offer to sell, sale, or importation of Lupin's Tablets, 48 mg and 145 mg, would infringe one or more of the claims of the '249 patent under 35 U.S.C. § 271.

ANSWER: Denied.

26. On information and belief, Lupin was aware of the existence of the '249 patent and was aware that the filing of its ANDA and certification with respect to the '249 patent constituted infringement of that patent. This is an exceptional case.

ANSWER: Lupin admits that Lupin Ltd. was aware of the existence of the '249 patent. Lupin denies all remaining allegations in Paragraph 26.

COUNT II

27. Plaintiffs incorporate each of the preceding paragraphs 1-22 [sic] as if fully set forth herein.

ANSWER: Lupin repeats, reasserts and incorporates by reference its answers to Paragraphs 1 through 22 above as if fully set forth herein.

28. By filing ANDA No. 90-856 for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Lupin's Tablets, 48 mg and 145 mg, prior to the expiration of the '802 patent, Defendants have committed an act of infringement, and/or induced infringement, of the '802 patent under 35 U.S.C. § 271(e)(2).

ANSWER: Denied.

29. The commercial manufacture, use, offer to sell, sale, or importation of Lupin's Tablets, 48 mg and 145 mg, would infringe one or more of the claims of the '802 patent under 35 U.S.C. § 271.

ANSWER: Denied.

30. On information and belief, Lupin was aware of the existence of the '802 patent and was aware that the filing of its ANDA and certification with respect to the '802 patent constituted infringement of that patent. This is an exceptional case.

ANSWER: Lupin admits that Lupin Ltd. was aware of the existence of the '802 patent. Lupin denies all remaining allegations in Paragraph 30.

* * *

Lupin denies all allegations not expressly admitted herein. Lupin further denies that Plaintiffs are entitled to any of the relief requested, or to any relief whatsoever, and requests that Plaintiffs' Complaint be dismissed with prejudice and that Lupin be awarded their fees and costs incurred defending this suit under 35 U.S.C. § 285.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer, without admitting allegations of the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on Plaintiffs, Lupin asserts the following separate defenses to the Complaint:

First Defense

The manufacture, use, sale, offer for sale, or importation of the fenofibrate tablets that are the subject of Lupin Ltd.'s ANDA, have not infringed, do not infringe, and will not, if marketed, infringe any valid and enforceable claim of the '249 patent or the '802 patent.

Second Defense

The claims of the '249 patent are invalid under one or more provisions of 35 U.S.C. § 101 *et seq*.

Third Defense

The claims of the '802 patent are invalid under one or more provisions of 35 U.S.C. § 101 *et seq*.

Fourth Defense

The Court lacks subject matter jurisdiction over any and all claims directed toward LPI.

Fifth Defense

LPI is not a proper party to this suit.

Sixth Defense

The Court lacks subject matter jurisdiction over any and all claims asserted under 35 U.S.C. §§ 271(a), (b), and/or (c).

Seventh Defense

The Complaint fails to state a claim upon which relief can be granted.

Eighth Defense

The Complaint fails to state an exceptional case claim.

Ninth Defense

Any additional defenses or counterclaims that discovery may reveal, including, but not limited to, defenses of unenforceability.

COUNTERCLAIMS

Lupin Limited ("Lupin Ltd.") and Lupin Pharmaceuticals, Inc. ("LPI") (collectively, "Lupin"), for their Counterclaims against Elan Pharma International Ltd. and Fournier Laboratories Ireland Ltd. (collectively, "Plaintiffs/Counterclaim-Defendants"), allege as follows:

The Parties

1. Lupin Ltd. is a corporation organized and existing under the laws of India, having a place of business at B/4 Laxmi Towers, Bandra-Kurla Complex, Bandra (W), Mumbai 400 051, India.

2. LPI is a corporation organized and existing under the laws of the Commonwealth of Virginia, having a place of business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland, 21202.

3. Elan Pharma International Ltd. purports to be an Irish corporation having a principal place of business at Monksland, Athlone, Co. Westmeath, Ireland.

4. Fournier Laboratories Ireland Ltd. purports to be an Irish corporation having its principal place of business at Anngrove, Carrigtwohill, Co. Cork, Ireland.

Jurisdiction and Venue

5. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*.; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

6. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under the MMA (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

7. This Court has personal jurisdiction over Plaintiffs/Counterclaim-Defendants because Plaintiffs/Counterclaim-Defendants have purposefully availed themselves of the rights and privileges of this forum by suing Lupin in this District, and because Plaintiffs/Counterclaim-Defendants conduct substantial business in, and have regular and systematic contacts with, this District.

8. Venue for these Counterclaims is proper in this District under 28 U.S.C. §§ 1391(b), (c) and 1400(b).

Patents-In-Suit

9. On or about April 23, 2002, the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 6,375,986 B1 ("the '986 patent"), entitled "Solid Dose Nanoparticulate Compositions Comprising A Synergistic Combination Of A Polymeric Surface Stabilizer And Dioctyl Sodium Sulfosuccinate," to Niels P. Ryde and Stephen B. Ruddy. A true and correct copy of the '986 patent is attached hereto as Exhibit A.

10. On or about October 2, 2007, the PTO issued U.S. Patent No. 7,276,249 B2 ("the '249 patent"), entitled "Nanoparticulate Fibrate Formulations," to Tuula Ryde, Evan E. Gustow,

Stephen B. Ruddy, Rajeev Jain, Rakesh Patel and Michael John Wilkins. A true and correct copy of the '249 patent is attached hereto as Exhibit B.

11. On or about January 22, 2008, the PTO issued U.S. Patent No. 7,320,802 B2 ("the '802 patent"), entitled "Methods of Treatment Using Nanoparticulate Fenofibrate Compositions," to Tuula Ryde, Evan E. Gustow, Stephen B. Ruddy, Rajeev Jain, Rakesh Patel and Michael John Wilkins. A true and correct copy of the '802 patent is attached hereto as Exhibit C.

12. The '986 patent, the '249 patent and the '802 patent are listed in FDA's Orange Book in connection with TRICOR®, as patents that allegedly "claim[] the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug."

13. On information and belief, Plaintiffs/Counterclaim-Defendants purport and/or claim to own and/or license, and/or to have the right to enforce, the '986 patent, the '249 patent and the '802 patent.

14. On or about March 6, 2009, Plaintiffs/Counterclaim-Defendants filed suit against Lupin in this District alleging infringement of the '249 patent and the '802 patent.

COUNT I
(Declaration of Non-Infringement of the '986 Patent)

15. Lupin realleges and incorporates by reference the allegations of Paragraphs 1-14.

16. A definite and concrete, real and substantial, justifiable controversy exists between Plaintiffs/Counterclaim-Defendants and Lupin regarding, *inter alia*, the non-infringement of the '986 patent which is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

17. The manufacture, use, sale, offer for sale or importation of the fenofibrate tablets that are the subject of Lupin Ltd.'s ANDA, have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '986 patent.

18. Lupin is entitled to a declaration that the manufacture, use, sale, offer for sale or importation of the fenofibrate tablets that are the subject of Lupin Ltd.'s ANDA, have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '986 patent.

COUNT II
(Declaration of Invalidity of the '986 Patent)

19. Lupin realleges and incorporates by reference the allegations of Paragraphs 1-18.

20. A definite and concrete, real and substantial, justifiable controversy exists between Plaintiffs/Counterclaim-Defendants and Lupin regarding, *inter alia*, the invalidity of the claims of the '986 patent which is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

21. The claims of the '986 patent are invalid under one or more provisions of 35 U.S.C. § 101 *et seq*.

22. Lupin is entitled to a declaration that the claims of the '986 patent are invalid.

COUNT III
(Declaration of Non-Infringement of the '249 Patent)

23. Lupin realleges and incorporates by reference the allegations of Paragraphs 1-22.

24. A definite and concrete, real and substantial, justifiable controversy exists between Plaintiffs/Counterclaim-Defendants and Lupin regarding, *inter alia*, the non-infringement of the '249 patent which is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

25. The manufacture, use, sale, offer for sale or importation of the fenofibrate tablets that are the subject of Lupin Ltd.'s ANDA, have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '249 patent.

26. Lupin is entitled to a declaration that the manufacture, use, sale, offer for sale or importation of the fenofibrate tablets that are the subject of Lupin Ltd.'s ANDA, have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '249 patent.

COUNT IV
(Declaration of Invalidity of the '249 Patent)

27. Lupin realleges and incorporates by reference the allegations of Paragraphs 1-26.

28. A definite and concrete, real and substantial, justifiable controversy exists between Plaintiffs/Counterclaim-Defendants and Lupin regarding, *inter alia*, the invalidity of the claims of the '249 patent which is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

29. The claims of the '249 patent are invalid under one or more provisions of 35 U.S.C. § 101 *et seq*.

30. Lupin is entitled to a declaration that the claims of the '249 patent are invalid.

COUNT V
(Declaration of Non-Infringement of the '802 Patent)

31. Lupin realleges and incorporates by reference the allegations of Paragraphs 1-30.

32. A definite and concrete, real and substantial, justifiable controversy exists between Plaintiffs/Counterclaim-Defendants and Lupin regarding, *inter alia*, the non-infringement of the '802 patent which is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

33. The manufacture, use, sale, offer for sale or importation of the fenofibrate tablets that are the subject of Lupin Ltd.'s ANDA, have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '802 patent.

34. Lupin is entitled to a declaration that the manufacture, use, sale, offer for sale or importation of the fenofibrate tablets that are the subject of Lupin Ltd.'s ANDA, have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '802 patent.

COUNT VI
(Declaration of Invalidity of the '802 Patent)

35. Lupin realleges and incorporates by reference the allegations of Paragraphs 1-34.

36. A definite and concrete, real and substantial, justifiable controversy exists between Plaintiffs/Counterclaim-Defendants and Lupin regarding, *inter alia*, the invalidity of the claims of the '802 patent which is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

37. The claims of the '802 patent are invalid under one or more provisions of 35 U.S.C. § 101 *et seq*.

38. Lupin is entitled to a declaration that the claims of the '802 patent are invalid.

REQUEST FOR RELIEF

WHEREFORE, Defendants Lupin Limited and Lupin Pharmaceuticals, Inc. respectfully requests that this Court enter a Judgment and Order in its favor and against Plaintiffs Elan Pharma International Ltd. and Fournier Laboratories Ireland Ltd. as follows:

(a) Declaring that the manufacture, use, sale, offer for sale or importation of the fenofibrate tablets that are the subject of Lupin Ltd.'s ANDA, have not

infringed, do not infringe, and will not, if marketed, infringe any valid and enforceable claim of the '986 patent;

(b) Declaring that the manufacture, use, sale, offer for sale or importation of the fenofibrate tablets that are the subject of Lupin Ltd.'s ANDA, have not infringed, do not infringe, and will not, if marketed, infringe any valid and enforceable claim of the '249 patent;

(c) Declaring that the manufacture, use, sale, offer for sale or importation of the fenofibrate tablets that are the subject of Lupin Ltd.'s ANDA, have not infringed, do not infringe, and will not, if marketed, infringe any valid and enforceable claim of the '802 patent;

(d) Declaring that the claims of the '986 patent are invalid;

(e) Declaring that the claims of the '249 patent are invalid;

(f) Declaring that the claims of the '802 patent are invalid;

(g) Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Lupin its attorneys' fees, costs, and expenses in this action; and

(h) Awarding Lupin any further and additional relief as the Court deems just and proper.

Jury Demand

Lupin demands a trial by jury on all issues so triable.

Dated: May 8, 2009

Respectfully submitted,

SAIBER LLC
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LOCAL CIVIL RULE 11.2 CERTIFICATION

Under Local Civil Rule 11.2, the undersigned counsel for Lupin hereby certifies that the United States Patent Nos. 6,375,986, 7,276,249, and 7,320,802 are also the subject of litigation in *Abbott Laboratories, et al. v. Lupin Limited, et al.*, Civil Action No. 2:09-cv-01007-SDW-MCA (D.N.J.)

Dated: May 8, 2009

s/Arnold B. Calmann
Arnold B. Calmann (abc@saiber.com)

LOCAL CIVIL RULE 201.1 CERTIFICATION

Under Local Civil Rule 201.1, the undersigned counsel for Lupin hereby certifies that Lupin seeks declaratory relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: May 8, 2009

s/Arnold B. Calmann
Arnold B. Calmann (abc@saiber.com)